



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,454	02/02/2001	Gregorio del Val	2001-0705	9327

20872 7590 09/16/2005

MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,454

Applicant(s)

VAL ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 6, 7, 12, 22, 23, 25, 27, 28, 31-33, 35, 37, 38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 7, 12, 22, 23, 25, 27, 28, 31-33, 35, 37, 38, 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Non-Final Rejection

Claims 1, 2, 4, 6, 7, 12, 22, 23, 25, 27, 28, 31-33, 35, 37, 38, and 41.

Applicant's traversal and the cancellation of claims 8, 10, 29, 30, and 39-40 in paper filed on 6/23/05 is acknowledged and considered by the examiner.

The indicated allowability of claims 1, 2, 4, 6, 7, 12, 22, 23, 25, 27, 28, 31-33, 35, 37, 38, and 41 is withdrawn in view of the newly discovered reference(s) to Buchanan et al. (cited on a PTO-1449) and Metcalfe et al., Critical Reviews in Food Science and Nutrition, 36, S165-S186, 1996. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6, 7, 12, 22, 23, 25, 27, 28, 31-33, 35, 37, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al (WO 99/20122) taken with Metcalfe et al. (Critical Reviews in Food Science and Nutrition, 36, S165-S186, 1996). Buchanan teaches that food allergies extend to a wide range of foods (page 16). Buchanan teaches a method of testing the allergenicity of food proteins comprising 1) sensitizing newborn atopic dogs (in-bred IgE producing dogs) by injecting a food protein, 2) challenging the dogs with the same food antigen that they received in the neonatal period, 3) observing the degree of the allergic response (pages 114-122). Buchanan teaches that more antibodies were produced by the immunized dogs than by controls (page 116). Each protein was in alum (page 114). Buchanan teaches using a skin test or food test in the method (page 117). Buchanan teaches that food that can be used in the test can be selected from soy, nuts, milk, whey, beef, egg, bread and other wheat products and other grain products (page 21). The step where the degree of allergic response observed in the step c) compared to step d) is indicative of the degree of allergenicity to a given allergen being tested. Step (e) correlating the data to humans would be obvious to one of ordinary skill in the art because one of ordinary skill understands that atopic dogs are used for determining

Art Unit: 1635

allergenicity expected in humans. However, while Buchanan teaches to test allergens from plants, Buchanan does not specifically teach using a heterologous protein produced by a “transgenic plant” in the method.

However, at the time the invention was made, Metcalfe teaches that prior to market introduction each food is subjected to extensive food, feed, and environmental safety assessments (page S165), including the use of animal models (page S180). If a gene is obtained from a known allergenic source and the protein encoded is expressed in a food component of the new plant variety, data should be generated to assure that the gene does not encode an allergen (page S166). The majority of individuals with documented immunologic reactions to foods exhibit immunoglobulin E (IgE)-mediated reactions (page S165).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Buchanan taken with Metcalfe, namely to test the allergenicity of a heterologous protein produced by a transgenic plant. One of ordinary skill in the art would have been motivated to combine the teaching and use the method to test the allergenicity of the heterologous protein in a transgenic plant because transgenic plants prior to market introduction are subjected to extensive assessments as taught by Metcalfe, which would require testing the allergenicity of the transgenic plant in an animal that could reasonably determine the allergenicity of the protein in humans (page S165).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Buchanan taken with Metcalfe, namely to use step d) in the method as the control step. One of ordinary skill in the art would have been motivated to combine the teaching and use the control step in step d) because one of

Art Unit: 1635

ordinary skill in the art understands that a control step is required to determine whether or not the heterologous protein is the source of the allergen and not an endogenous protein from the plant or another source.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments, page 9, filed 6/23/05, with respect to 112 first paragraph new matter rejection have been fully considered and are persuasive. The rejection of claims 8, 10, 29, 30, and 39-40 has been withdrawn because of the cancellation of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Art Unit: 1635

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

Joe Wanta
AU 1635